CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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# POCT04-A2

## Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline—Second Edition

This document provides guidance to users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory, to ensure reliable results comparable to those obtained within the clinical laboratory.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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# Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline—Second Edition

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## Abstract

Clinical and Laboratory Standards Institute document POCT04-A2—*Point-of-Care* In Vitro *Diagnostic (IVD) Testing; Approved Guideline—Second Edition* provides users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory with information and suggestions for good laboratory practice and for producing reliable test results regardless of where the test is performed. Point-of-care testing (POCT), also known as bedside testing or near-patient testing, is intended to provide more rapid test results than can be achieved in central or satellite laboratory settings. This is important particularly in critical care areas, such as the intensive care unit, emergency rooms, burn units, emergency transport vehicles, and operating rooms, as well as in skilled nursing facilities and hospices. POCT has also been used to expedite treatment decisions and provide convenience for the patient/client.

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## Foreword

As a result of pressures from outside and within, the healthcare community is reevaluating how to best deliver services to society in a complex healthcare system. Part of this examination concerns the delivery of laboratory services to patients/clients.

Medical conditions, physical location of the patient/client, and treatment regimens often require laboratory results to be obtained quickly, so appropriate medical care can be administered without delay. Laboratory medicine professionals have been challenged by the increasing demands for faster turnaround of results, but at the same time are faced with limitations in providing these services, imposed in part by cost constraints.

With the advent of portable testing instruments capable of producing results within minutes, which augment dipsticks and other noninstrumented testing systems (e.g., occult blood testing), point-of-care testing (POCT) (also referred to as near-patient testing or bedside testing) has evolved as one way to meet these demands. Because of the enormous consequences of unreliable test results, it is vital that results continue to be reliable and of high quality as these tests are transferred from the clinical laboratory to the point of care.

One of the challenges facing the healthcare community is acceptance of the idea that laboratory testing, traditionally performed by and under the supervision of trained laboratory personnel, will, in many instances, be performed by personnel not trained in clinical laboratory practice. This concern applies both within and outside the traditional laboratory community. It is the responsibility of the manufacturer to provide test systems capable of delivering reliable results when used properly by the testing personnel. Once the decision to offer POCT has been made, professionals in laboratory medicine should be involved to support and assess the results of these services.

POCT has been, and will continue to be implemented in a wide range of locations. It is up to each hospital, nursing home, emergency service provider, insurance company, home healthcare delivery network, etc., to assess its POCT needs. This document provides information on how to proceed in assessing those needs and in the evaluation and implementation of POCT.

It is the intent of the Subcommittee on Point-of-Care Testing that this guideline provides useful information to those wishing to perform POCT. The guideline was written under the assumption that its primary users will be nonlaboratory healthcare personnel. Therefore, we have attempted to provide definitions, procedures, and recommendations that are both educational and practical. In addition, the format is designed to be user-friendly and easy to follow.

This document replaces the approved guideline, AST2-A, which was published in 1995. Several changes have been made in this edition; chief among them is the introduction of the concept of alternative quality control (AQC), in Section 18.4.2, for point-of-care testing sites. The document has also been revised to include guidance for point-of-care programs outside the U.S., as well as updated regulatory recommendations for U.S.-based programs. This guideline also contains updated recommendations regarding patient specimen collection and identification (see Section 16) and a newly developed training checklist (see Appendix E).

**Key Words**

Calibration, point-of-care testing, quality assurance, quality control, safety

# Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline—Second Edition

## 1 Scope

There are many potential sites for POCT. Test operators may include nurses and physicians in acute care units in hospitals and emergency rooms; cardiac perfusionists in operating rooms; visiting home nurses in patients'/clients' homes; emergency medical technicians in ambulances; nurses in clinics, schools, and colleges; pharmacists and pharmacy technicians in pharmacies; and nonhealthcare workers at various employment settings, such as drug rehabilitation centers, law enforcement facilities, public screening sites, and insurance companies. A physician's office laboratory (POL) is another example of a setting for POCT. Patient self-testing and the handling of results generated by it are outside the scope of this document. Additionally, this guideline only applies to tests that involve the collection of patient specimens. Thus, analytical devices such as transcutaneous meters and continuous glucose monitoring devices are outside the scope of this document.

## 2 Introduction

Advances in technology and the implementation of microtechniques and portable instruments have made it possible to move laboratory testing closer to the patient/client. Point-of-care testing (POCT), is intended to provide more rapid and accessible test results than can be achieved in central or satellite laboratory settings. This is particularly important in critical care areas, such as the intensive care unit, emergency rooms, burn units, emergency transport vehicles, and operating rooms, as well as skilled nursing facilities, hospices, etc. POCT has also been used to expedite treatment decisions and provide convenience for the patient/client. The latter is significant in ambulatory outpatient settings (physician offices, clinics, etc.) where POCT has become an important form of diagnostic testing. The following guideline provides information and suggestions for good laboratory practice and for producing reliable test results, regardless of where testing is performed.

## 3 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol*. 1996;17(1):53-80). For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to the most current edition of CLSI document M29—*Protection of Laboratory Workers From Occupationally Acquired Infections*.

## 4 Definitions

**accuracy (of measurement)** – **1)** closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93)[1]; **2)** true or target value; freedom from error; **NOTE:** The accuracy of results can be measured by comparing them to results accepted as correct (e.g., standard methods), or by comparing them with those from another laboratory that uses a comparable method (this is "relative accuracy").